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Comparison of manual compression with a new bioabsorbable vascular closure device in percutaneous peripheral procedures

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Abstract
Aim: The aim of this study was to see how well a new bioabsorbable vascular closure device (VCD) performs in comparison with manual compression (MC) for access-site hemostasis in patients undergoing percutaneous peripheral procedures.
Material and Methods: This retrospective cohort study was carried out by examining the files of patients who underwent vascular intervention for peripheral artery disease at Ordu University Training and Research Hospital between February 1, 2019, and January 31, 2020. The cases were divided into two groups according to the method of achieving access-site hemostasis (MC or VCD).
Results: The patients' mean age was 64.81 ± 11.03 years, and 75.3% were males. There were 41 cases in the MC group and 40 cases in the VCD group. The frequency of hyperlipidemia in the VCD group was significantly higher than in the MC group (65.0% vs. 31.7%, p = 0.003). Time to hemostasis (TTH), time to ambulation (TTA), and length of hospital stay were significantly greater in the MC group than in the VCD group (p<0.001 for all). No major complications were observed in the VCD group, whereas 5 (6.2%) patients in the MC group developed complications (p = 0.023).
Discussion: The use of VCD appears to be associated with shorter TTH, TTA, and length of hospital stay, and major complications were less frequent in the VCD group.

Keywords
Percutaneous Administration, Vascular Closure Device, Hemostasis, Ambulation, Peripheral Arterial Disease

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Introduction

Manual compression (MC) is the gold-standard method for obtaining hemostasis after vascular interventional operations, but it is well established to be problematic for patients due to extended immobilization and the need for prolonged application of inguinal pressure [1]. This situation has motivated the research and development of vascular closure devices (VCDs) to decrease adverse effects and shorten the time to ambulation (TTA) [1]. The application of MC for hemostasis after femoral arterial puncture involves strong compression at the puncture site (around 15 minutes) and bed rest (extending to half a day). In addition to patient-related problems such as extended hospitalization and loss of time for hospital staff, MC has been associated with rebleeding risks [1].

VCDs have been demonstrated to be effective alternatives to MC in many patient groups (4) including anticoagulation recipients and those with repeat procedures. In a randomized comparison of VCD and MC in recipients of diagnostic procedures, VCD was found to shorten the time to hemostasis (TTH) and TTA. It has been shown that high-puncture antegrade approach to the femoral artery increases groin hematoma and retroperitoneal bleeding risks, while low punctures have been linked to the development of arteriovenous fistula and pseudoaneurysms [2]. Studies investigating VCDs in antegrade femoral punctures have shown that these devices are safe and reliable options [2]. However, there are few studies in the literature examining the use of VCD after a retrograde approach from the popliteal artery. Thus, the aim of this study was to compare a bioabsorbable VCD (Angio-seal VCD) with MC in terms of efficacy in providing hemostasis at the access site in patients undergoing percutaneous peripheral operations.

Material and Methods

This retrospective cohort study was carried out by examining the files of patients who underwent vascular intervention for peripheral artery disease at Ordu University Training and Research Hospital between February 1, 2019, and January 31, 2020. Ethical approval for the study was obtained from Ordu University Clinical Research Ethics Committee (No 2021/111).

Patients

Patients were excluded from the study using the following criteria:

- Acute coronary artery disease or upper extremity artery disease
- Diagnosis of uncontrolled hypertension (blood pressure 180/110 mmHg) at closure
- Previous vascular grafting or femoral vascular surgery or diagnostic procedures in/from the same site
- Pre-existing platelet disorder, bleeding disorder (abnormal platelet count or international normalized ratio), systemic disease, or skin infection at the site
- Fluoroscopically observable calcium deposits, atherosclerotic lesions, or previously placed stents within a distance of 1 cm (distal or proximal) from the puncture site due to the possibility of complicating VCD application

Vascular interventions were performed on 155 patients during the study period, 81 of whom met the inclusion criteria. The cases were divided into two groups according to the application of post-procedural hemostasis, and there were 41 patients in the MC group and 40 patients in the VCD group.

Variables

The parameters examined in the study were as follows: patient characteristics (age, gender, body mass index [BMI], comorbidities, smoking status), procedure-related features (type of approach [antegrade, retrograde], localization [femoral, popliteal], and sheath size), and post-procedural clinical features (TTA, TTH, length of hospital stay and complications).

Procedure and application of hemostasis

All patients underwent magnetic resonance imaging (MRI) angiography or computed tomography (CT) angiography before the intervention. At least 5000 IU of heparin was administered to the cases during the procedure, and low-molecular-weight heparin (LMWH) was applied after the procedure. Additionally, clopidogrel and cilostazol were prescribed after procedures when deemed necessary according to the lesion and the treatment applied.

As a new bioabsorbable device, the Angio-seal VCD (St. Jude Medical, Minnetonka, Minnesota) is applied using three major components: a collagen plug, an intra-arterially-deployed absorbable polymer anchor, and a suture applied under the skin. The collagen plug is squeezed between the suture and the anchor to facilitate hemostasis with the pressure provided by the whole structure. It is supplied in two sizes: 6-F and 8-F [2]. There were no requirements for Doppler ultrasonography (USG) in femoral artery punctures. However, popliteal artery punctures were always performed under Doppler USG guidance. Femoral angiographies were taken after completion of the interventional operations. The patients underwent VCD after its application was designated as a procedure that is covered by insurance (according to various criteria discussed below). Before the coverage was accepted by insurance, all patients had undergone MC. Procedures for the application of the Angio-seal VCD were carried out in the interventional radiology department right after treatment.

After confirmation of insurance coverage and at the time of the angioplasty operation, all patients were assessed for the possibility of Angio-seal VCD application. Patients with severely calcified femoral arteries and those with multiple plaques did not undergo Angio-seal application. Depending on the severity of the procedure and the material to be used, 6-F or 7-F sheaths were placed. The median (interquartile range, IQR) VCD size was 8 (6 – 8) mm. All patients received the same type of Angio-seal. Briefly, the guidewire of the Angio-seal device was routed through the 6-F sheath, and the vascular sheath was withdrawn under manual compression. The sheath of the Angio-seal device was then inserted into the artery over the previously placed guidewire (A), and the anchor was carefully placed in the appropriate position (B). Finally, closure with the anchor and suture was achieved by squeezing the arterial plug towards the arterial wall (C, D) (Figure 1).

In the MC group, manual compression was applied for 10-20 minutes, and then a sandbag was placed to exert sufficient pressure for 4 hours. The cases were mobilized 8 hours later as a standard procedure. Sandbags were not used in the VCD group, only a compressive bandage was applied. Hemostasis was achieved in the femoral artery immediately after the

procedure.

Hemostasis evaluation and clinical follow-up

Successful closure with the Angio-seal VCD was defined through confirmation of the following: placement of the plug, extraction of the delivery system, and hemostasis within 5 minutes. In all patients with device failure, TTH was greater than 5 minutes. Manual compression was required in two VCD patients who underwent the procedure using the femoral retrograde approach because the VCD was unsuccessful with this particular approach. These two cases were excluded from the study. CT angiography or color-coded duplex sonography was used to assess puncture site problems. No complications were identified in any of the patients (Figure 2). TTH was defined as the time from the removal of the introducer sheath until hemostasis was achieved. The time to ambulation (TTA) was considered as the period from the withdrawal of the introducer sheath to the patient being able to stand and walk 20 feet without reappearance of bleeding.

All related complications were noted in both the MC and Angio-seal VCD groups, including re-bleeding at the operation site. Femoral pulses of both lower extremities were examined before the intervention, shortly after, and during recovery. On the first postoperative day, patients were examined for the development of ecchymosis, swelling, mass infection, or murmur at the intervention site, and palpation was performed. Major complications (ecchymosis or hematoma larger than 6 cm, pseudoaneurysm, arteriovenous fistula, and retroperitoneal hemorrhage) and minor complications (ecchymosis or hematoma smaller than 6 cm) were recorded. Additionally, patients who had undergone baseline duplex USG were subjected to follow-up ultrasound examination of the site on the 30th day after intervention.

Statistical analysis

The software SPSS version 21.0 was used to perform all statistical analyses (IBM, Armonk, NY). The normality of distributions was checked via the Shapiro-Wilk test. Data are presented as the mean ± standard deviation (SD) or median (1st – 3rd quartile range [IQR]) for continuous variables according to the normality of distributions and as frequency (percentage) for categorical variables. Normally distributed continuous variables were compared using an independent-sample t-test, while non-normally distributed variables were compared with the Mann-Whitney U test. The distribution of categorical variables was examined using chi-squared tests. Two-tailed p-values less than 0.05 were considered statistically significant.

Results

The mean age of the study group was 64.81±11.03 years, and 75.3% of the cases were males. There were 41 cases in the MC group and 40 cases in the VCD group. The frequency of hyperlipidemia in the VCD group was significantly higher than in the MC group (65.0% vs. 31.7%, p=0.003). No significant difference between the groups was found in terms of other comorbidities, age, gender, BMI, and smoking status (p>0.05 for all) (Table 1).

In the MC group, TTH (Figure 3) and length of hospital stay were significantly longer than in the VCD group (p<0.001 for all). No major complications were observed in the VCD group,

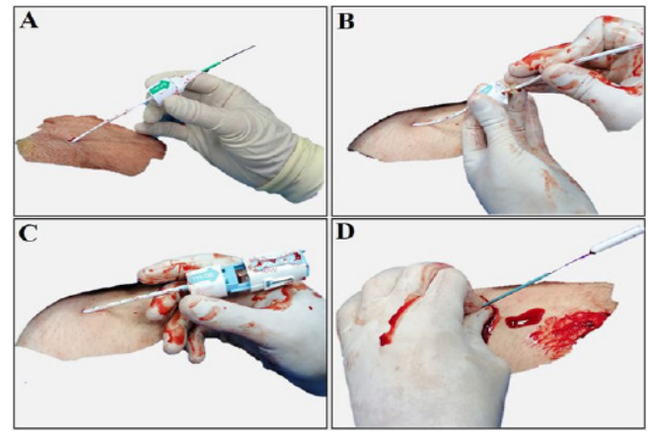

Figure 1. (A) Angioseal package was passed over the guidewire and placed in the artery.(B,C) After the device was deployed through the sheath, the anchor was placed.(D) Finally, the anchor was retracted, and the puncture was closed by pressing the arterial plug toward the arterial wall.

Table 1. Summary of patient characteristics with regard to groups

	Group		All (n=81)	P
	MC (n=41)	VCD (n=40)		
Gender				
Male	32 (78.0%)	29 (72.5%)	61 (75.3%)	0.563
Female	9 (22.0%)	11 (27.5%)	20 (24.7%)	
Age (years)	64.00 ± 10.80	65.65 ± 11.34	64.81 ± 11.03	0.504
BMI (kg/m2)	26 (24 - 28)	26 (25 - 27.5)	26 (24 - 28)	0.848
Comorbidity				
Hyperlipidemia	13 (31.7%)	26 (65.0%)	39 (48.1%)	0.003
Diabetes mellitus	21 (51.2%)	25 (62.5%)	46 (56.8%)	0.306
Hypertension	34 (82.9%)	29 (72.5%)	63 (77.8%)	0.259
CRF	3 (7.3%)	2 (5.0%)	5 (6.2%)	0.665
CAD	9 (22.0%)	4 (10.0%)	13 (16.0%)	0.143
Smoking	16 (39.0%)	19 (47.5%)	35 (43.2%)	0.441

Data are given as mean ± standard deviation or median (1st quartile - 3rd quartile) for continuous variables according to normality of distribution and as frequency (percentage) for categorical variables. BMI: Body mass index, CAD: Coronary artery disease, CRF: Chronic renal failure, MC: Manual compression VCD: Vascular closure device

Table 2. Summary of clinical features with regard to groups

	Group		All (n=81)	p
	MC (n=41)	VCD (n=40)		
Approach				
Femoral antegrade	10 (24.4%)	10 (25.0%)	20 (24.7%)	
Femoral retrograde	21 (51.2%)	20 (50.0%)	41 (50.6%)	0.994
Popliteal retrograde	10 (24.4%)	10 (25.0%)	20 (24.7%)	
Sheath size (Fr)	6 (6 - 7)	7 (6 - 7)	7 (6 - 7)	0.056
6	22 (53.7%)	13 (32.5%)	35 (43.2%)	0.055
7	19 (46.3%)	27 (67.5)	46 (56.8%)	
Time to ambulation (hour)	8 (8 - 8)	3 (3 - 4)	8 (3 - 8)	<0.001
Time to hemostasis (min)	15 (10 - 20)	3 (3 - 4)	10 (3 - 15)	<0.001
Length of hospital stay (day)	2 (2 - 2)	1 (0.5 - 1)	2 (1 - 2)	<0.001
Complications				
Major	5 (12.2%)	0 (0%)	5 (6.2%)	0.023
Minor	6 (14.6%)	3 (7.5%)	9 (11.1%)	0.307

Data are given as mean ± standard deviation or median (1st quartile - 3rd quartile) for continuous variables according to normality of distribution and as frequency (percentage) for categorical variables. MC: Manual compression VCD: Vascular closure device

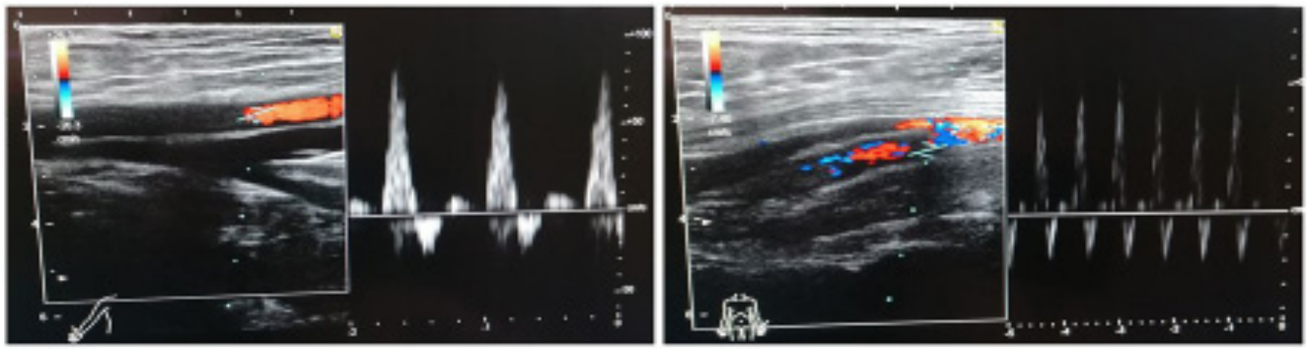

Figure 2. Doppler ultrasonographic examination in the follow-up of patients in the VCD group (Femoral (A) and popliteal artery (B) flow is normal, vessel walls are smooth, and there is no occlusion in the vessel diameter).

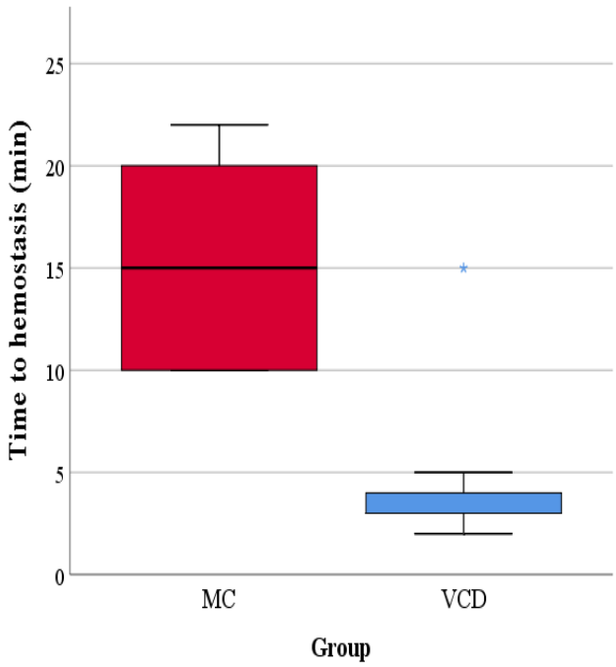

Figure 3. Time to hemostasis with regard to groups

but 5 (6.2%) patients in the MC group had major complications: retroperitoneal hemorrhage, AV fistula, embolism in the lower extremity, ecchymosis + hematoma (>6cm), and pseudoaneurysm. The frequency of major complications was significantly higher in the MC group than the VCD group (p= 0.023). All 9 minor complications recorded in the two groups were defined as ecchymosis + hematoma (Table 2). Two of the patients in the MC group received blood transfusions.

Discussion

The disadvantages or shortcomings of MC application are well described and include patient-related problems (related to groin pressure and extended bed rest), intensive workload for medical personnel, and longer hospitalization. The advantages of VCDs, including the Angio-seal VCD, are earlier vascular sheath removal, swift hemostasis, earlier ambulation, shorter hospitalization, and decreased staff workload [3]. This study revealed that TTA, TTH, and length of hospital stay were significantly shorter with the use of VCD, and major complications were significantly less frequent.

Cox et al. recently performed a systematic review of 34 randomized controlled trials comparing VCD and MC applications [3]. They also found that TTH, TTA, and length of hospital stay were significantly shortened with the use of VCD in comparison to MC. Noori et al. also described similar findings in another systematic review of 34 articles [4]. Wong et al. found that VCD use significantly decreased mean TTH (4.4 min vs. 11.6 min) and mean TTA (2.5 h vs. 5.0 h) [5]. Similarly, a randomized controlled study reported that TTA, TTH, and hospitalization durations were lower in the Angio-seal group.

Considering the results of our study, which are compatible with previous studies, VCD is quite advantageous in terms of clinical outcomes in comparison to MC. In our study, the most prominent finding was thought to be the shortening of TTH, which is a benefit that is associated with the shortening of TTA and length of hospital stay. Therefore, VCD application can be more beneficial than MC, especially with respect to decreased TTA and patient-related advantages [6].

Another important finding of our study was that no major complications were observed in these patients, although minor ecchymosis + hematoma was observed in a few cases in the VCD group. In the VCD group, acute arterial occlusion and pseudoaneurysm were not identified. The low complication rate in our study is consistent with prior research [7]. In contrast, 12.2% of the MC group had major complications.

Previous studies on this subject have reported different results in terms of complication rates. First, we examined the results that are compatible with our study. Vaitkus et al. found a lower risk of vascular complications with VCD use (except for hematoma development) in their 5000-patient meta-analysis of access site complications. With the 6-Fr EXOSEAL system, Schmelter et al. showed a high success rate of 96%, fewer vascular problems (7%), and no severe complications.

In a prospective study including the records of nearly 13,000 consecutive patients from 2002 to 2007, fewer vascular complications were found with the use of VCD than MC in "appropriately selected patients undergoing diagnostic and therapeutic cardiac catheterizations [8]. In some studies, researchers have observed no significant variations in the incidence of complications across the groups. For instance, two recent systematic reviews have shown that the frequency of complications was similar in MC and VCD groups. Furthermore, VCD and MC were shown to have similar rates of periprocedural or access site complications [9]. Specifically, in a study comparing Angio-seal and MC, Alshehri et al. showed that the frequency of major complications did not change significantly

between the groups, while the frequency of minor complications was significantly increased in the MC group [10].

Nonetheless, it has also been reported that complications increase with VCD use. In a study comparing Angio-seal and MC applications after endovascular interventions in peripheral artery disease, Fokkema et al. reported that the use of Angio-seals increased the risk of developing any complications (especially hemorrhage), regardless of other parameters. The authors emphasized that the Angio-seal system should be used carefully as it can increase the complication rate [11]. Similarly, there are different studies reporting an increase in complications with VCD methods [12]. It is thought that the different results reported in the studies may have been caused by differences in VCD devices and the experience of the practitioner.

Important limitations of our study include the fact that this is a retrospective study (therefore there was no randomization of groups) and it involved only a single center. Furthermore, a single type of VCD (St. Jude Medical, Minnetonka, Minnesota) with limited size options (6-F and 8-F) was used, thus it could not be compared to other devices. When discussing other studies, our comments were made with respect to the comparisons with MC, and the differences that may occur due to brand or model differences were not taken into consideration. Thus, the present arguments and inferences cannot be generalized to other types of VCDs. Although the frequency of hyperlipidemia was different between the groups, it is believed that this difference did not affect the results of our study.

Conclusion

With the utilization of the Angio-seal VCD, we found that TTH, TTA, duration of hospitalization, and major complication frequency were decreased in comparison to those with MC. After peripheral vascular interventions, the Angio-seal VCD appears to be a safe and effective method of arteriotomy closure, as demonstrated by our findings in patients undergoing single closure of percutaneous femoral and popliteal access. Nevertheless, in future studies, it would be useful to compare different VCD devices with a large number of cases.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

None of the authors received any type of financial support that could be considered potential conflict of interest regarding the manuscript or its submission.

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